

Rec'd PCT/PTO 21 SEP 2005  
10/528691  
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q86966

Gunnar Leo KARUP, et al.

Appln. No.: 10/528,691

Group Art Unit: Not Yet Known

Confirmation No.: 4613

Examiner: Not Yet Known

Filed: March 22, 2005

For: NOVEL RALOXIFENE ACID ADDITION SALTS AND/OR SOLVATES THEREOF,  
IMPROVED METHOD FOR PURIFICATION OF SID RALOXIFENE ACID  
ADDITION SALTS AND/OR SOLVATES THEROF AND PHARMACEUTICAL  
COMPOSITION COMPRISING THESE

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action

INFORMATION DISCLOSURE STATEMENT

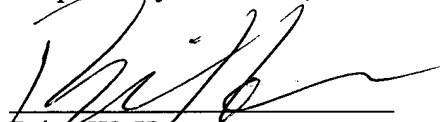
U.S. Appln. No.: 10/528,691

on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

  
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WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: September 21, 2005

Substitute for Form 1449 A & B/PTO  <b><u>INFORMATION DISCLOSURE</u></b> <b><u>STATEMENT BY APPLICANT</u></b>  <i>(use as many sheets as necessary)</i>				<i>Complete if Known</i>	
				Application Number	10/528,691
				Confirmation Number	4613
				Filing Date	March 22, 2005
				First Named Inventor	Gunnar Leo KARUP
				Art Unit	Not Yet Known
Examiner Name	Not Yet Known				
Sheet	1	of	2	Attorney Docket Number	Q86966

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US 5,852,193		12/22/1998	Chelius
		US 4,418,068		11/29/1983	Jones
		US 4,133,814		01/09/1979	Jones, et al.

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		WO	02/42289	A2	05/30/2002	ELI LILLY AND COMPANY	
		WO	00/35485	A1	06/22/2000	ORION CORPORATION	
		WO	97/34888		09/25/1997	ELI LILLY AND COMPANY	
		WO	96/40677		12/19/1996	ELI LILLY & COMPANY	
		WO	97/35571		10/02/1997	ELI LILLY AND COMPANY	
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		WO	97/30709		08/28/1997	ELI LILLY AND COMPANY	
		WO	98/48792		11/05/1998	ELI LILLY AND COMPANY	
		WO	98/48787		11/05/1998	ELI LILLY AND COMPANY	
		WO	98/22456		05/28/1998	ELI LILLY AND COMPANY	
		WO	98/13369		04/02/1998	Merck Sharp & Dohme Limited	
		WO	96/40693		12/19/1996	ELI LILLY AND COMPANY	
		WO	97/34888		09/25/1997	ELI LILLY AND COMPANY	
		WO	96/40691		12/19/1996	ELI LILLY AND COMPANY	
		WO	96/40676		12/19/1996	ELI LILLY AND COMPANY	
		WO	95/34536		12/21/1995	ELI LILLY AND COMPANY	
		WO	2005/003116	A1	01/13/2005	ER-REGIERRE S.p.A.	
		WO	2004/029046	A2	04/08/2004	AS/GEA Farmaceutisk Fabrik	
		WO	02/42261	A2	05/30/2002	ELI LILLY AND COMPANY	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>
		Antiestrogens. 2. <sup>1</sup> Structure-Activity Studies in a Series of 3-Aroyl-2-arylbenzo [b] thien-3-yl[4-[2-(1-piperidinyl) ethoxy]-phenyl]methanone Hydrochloride (LY156758), a Remarkably Effective Estrogen Antagonist with Only Minimal Intrinsic Estrogenicity, by C.D. Jones, et al. "J. Med. Chem., vol. 27(8), 1057-1066	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to indicate here if English language Translation is attached.